UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,774	06/27/2003	Jeffrey Karl Sutton	101896-0163	8137

21125 7590 07/18/2006

NUTTER MCCLENNEN & FISH LLP
WORLD TRADE CENTER WEST
155 SEAPORT BOULEVARD
BOSTON, MA 02210-2604

EXAMINER	
ROGERS, KRISTIN D	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 07/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,774	SUTTON ET AL.	
	Examiner	Art Unit	
	Kristin D. Rogers	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☒ Claim(s) *1* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed April 11, 2006 have been fully considered and the claim objection of claims 1-3, 14, and 18, regarding the usage of "the" prior to the phrase "at least one opening" is persuasive. Objection withdrawn.

2. The Examiner acknowledges Applicant's arguments regarding the claim rejections under 35 U.S.C. § 102(b), however they are not persuasive. As broadly as structurally claimed the Bryan et al. reference as cited teaches as disclosed an outer cannula with a closed distal end (Figure 14). In response to applicant's argument that the outer cannula of Bryan et al. is incapable of sampling tissue, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

The Examiner further notes that rejection of claims 1, 5-6, 11-14, and 17 under 35 U.S.C. § 102(b) is improper and has been withdrawn. In view of the publication date of the Bryan (6488636) reference, claims 1, 5-6, 11-14, and 17 are newly rejected under 35 U.S.C. § 102(e).

Claim Objections

3. Claim 1 is objected to because of the following informalities: the phrase "...defining a inner lumen..." should recite, "defining an inner lumen". Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1, 5-6, 11-14, and 17 are rejected under 35 U.S.C. 102(e) as being anticipated by Bryan et al (6488636). In regard to claim 1, Bryan et al. teaches a sampling device with an inner cannula 16 and outer cannula 12 that are selectively moveable, an outer cannula 12 with a closed distal end and penetrating tip 13 and a plurality of openings 114 in the sidewall, an inner cannula 16 is aligned with openings 112 in the sidewall. In regard to claim 5, Bryan et al. shows a bone marrow sampling device an inner cannula 16 with a closed distal end, Figure 3. In regard to claim 6, Bryan et al. shows a biological tissue-sampling device with an inner cannula 16 with a plurality of openings 15 in the sidewall. In regard to claim 11, Bryan et al. teaches a sampling device with an inner cannula 16 and outer cannula 12 that are selectively

moveable, an outer cannula 12 with a closed distal end and penetrating tip 13 and a plurality of openings 114 in the sidewall, an inner cannula 16 is aligned with openings 112 in the sidewall, and a suction knob 66 on the proximal end of the inner cannula. In regard to claims 12,13 and 14, Bryan et al. teaches a sampling device with an inner cannula 16 and outer cannula 12 that are selectively moveable, an outer cannula 12 with a closed distal end and penetrating tip 13 and a plurality of openings 114 in the sidewall, an inner cannula 16 is aligned with openings 112 in the sidewall, a second inner cannula 24 without openings in the sidewall, and is selectively movable with respect to the outer and inner cannula. In regard to claim 17, Bryan et al. teaches a sampling device with outer cannula 12 with a closed distal end and penetrating tip 13 and a plurality of openings 114 in the sidewall arranged in a helical pattern.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 1-7, 8-11 and 16-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Burbank et al. (20020193705). In regard to claim 1, Burbank et al. shows a bone marrow sampling device, comprising: an outer cannula 152 having a sidewall defining a inner lumen and a closed distal end with a tissue penetrating tip, the sidewall having a plurality of openings formed therein and spaced apart at different radial and longitudinal positions on the sidewall 218, wherein each opening is in fluid

communication with the inner lumen of the outer cannula; an inner cannula having a sidewall defining an inner lumen 116, the inner cannula being adapted to be disposed within and mated to the outer cannula such that the outer cannula and inner cannula are selectively moveable with respect to each other; and at least one opening formed in the sidewall of the inner cannula , wherein selective relative movement of the inner cannula and the outer cannula enables the device to be configured in multiple bone marrow sampling modes in which the at least one opening in the sidewall of the inner cannula is aligned with different openings in the sidewall of the outer cannula such that bone marrow can be drawn into the inner lumen of the inner cannula from different radial and longitudinal positions external to the sidewall of the outer cannula without the need to reposition the outer cannula (figures 7 and 8). In regard to claims 2-4, it is obvious that the withdrawal aperture of the inner and outer cannula has a diameter of 0.5 mm to 3.0 mm; having an open surface area in the range of 0.5mm^2 to 8 mm^2 ; and the outer cannula has a diameter in the range of 0.7 mm to 6 mm (Figures 7 and 8). In regard to claim 5, the inner cannula has a closed distal end 212. In regard to claim, the inner cannula has a plurality of openings in the sidewall 234 of Figure 8. In regard to claims 8, 9 and 10, the movement between the inner and outer cannula is translational and rotational (abstract). In regard to claim 11, the proximal end of the inner cannula is mated with a suction device 108. In regard to claim 16, the movement between the inner and outer cannula is automated 112. In regard to claim 17, the openings in the outer cannula sidewall follow a helical pattern (Figure 7).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 2-3, 7 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan et al as applied to claim 1 above and in view of Krueger (20030050574). In

regard to claim 2, Bryan et al shows a sampling device with an inner cannula 16 and outer cannula 12 an outer cannula 12 with a closed distal end and penetrating tip 13 and a plurality of openings 114 in the sidewall, an inner cannula 16 is aligned with openings 112 in the sidewall. Bryan et al. lacks disclosure of the diameter of the withdrawal aperture. Krueger teaches the claimed invention where the openings of the outer and inner cannula create a withdrawal aperture 16 where the size of the openings may vary for the purpose of providing a space large enough to permit encroachment of sampled tissue (page 3 column 1, paragraph 37). It would have been obvious for one having ordinary skill in the art at the time of the invention to modify Bryan et al. with withdrawal apertures on the inner and outer cannula where the diameter of the openings can range from 0.5mm to 3mm in order to provide a sampling space for biological material. In regard to claim 3, Bryan et al. doesn't teach the alignment of the inner and outer cannula creating a withdrawal aperture. Krueger teaches the claimed invention where the openings of the outer and inner cannula create a withdrawal aperture in the range of $0.5mm^2$ to $8mm^2$ (page 3, column 1, paragraph 37). It would have been obvious for one having ordinary skill in the art at the time of the invention to modify Bryan et al. with withdrawal apertures on the inner and outer cannula with a diameter $0.5mm^2$ to $8mm^2$ as taught by Krueger for the purpose of providing a sampling space for biological material. In regard to claim 7, Bryan et al. teaches a sampling device with an inner cannula 16 and outer cannula 12 that are selectively moveable, an outer cannula 12 with a closed distal end and penetrating tip 13 and a plurality of openings 114 in the sidewall, an inner cannula 16 is aligned with openings 112 in the

sidewall. Bryan et al. does not disclose the minimum distance between the openings in the sidewall. Krueger teaches a biological tissue biopsy device that shows the openings in the sidewall 16 at least 5mm apart. Therefore, it would have been obvious for one having ordinary skill in the art at the time of the invention to modify Bryan et al. with a cannula that has sidewall openings spaced at least 5mm apart as taught by Krueger to meet the structural limitations of the claimed invention. In regard to claim 18, Bryan et al. lacks indicia on the outer and inner cannula. Krueger teaches a biological tissue biopsy device with indicia 17 on the exterior surface of the inner and outer cannula for providing orientation markers (Figures 1 and 4). Therefore, it would have been obvious for one having ordinary skill in the art at the time of the invention to modify Bryan et al. with indicia on the outer and inner cannula as taught by Krueger since such modification would provide and indication of the alignment of the inner and outer cannula.

12. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan et al. in view of Van Bladel et al. (2003/0093008). Bryan et al. teaches the claimed sampling device with an inner cannula 16 and outer cannula 12 that are selectively moveable, an outer cannula 12 with a closed distal end and penetrating tip 13 and a plurality of openings 114 in the sidewall, an inner cannula 16 is aligned with openings 112 in the sidewall. Bryan et al. lacks disclosure of the dimensions of the outer cannula. Van Bladel et al. teaches a biological tissue biopsy device with an outer and inner cannula, 5 and 20 respectively, where the outer cannula has a diameter of 3mm. It would have been obvious for one having ordinary skill in the art at the time of the invention to modify Bryan et al. with an outer cannula with a diameter of 3mm as taught

by Bladel et al. for the purpose of meeting the structural limitations of 0.7mm to 6mm as stated in the claimed invention.

13. Claims 8 to 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan et al. in view of Akerfeldt et al. (5810826). In regard to claims 8, 9, and 10, Bryan et al. teaches a sampling device with an inner cannula 16 and outer cannula 12 that are selectively moveable, an outer cannula 12 with a closed distal end and penetrating tip 13 and a plurality of openings 114 in the sidewall, an inner cannula 16 is aligned with openings 112 in the sidewall. Bryan lacks an inner and outer cannula with translational and rotational movement. Akerfeldt et al. teaches a puncturing device comprising an inner cannula 5 and outer cannula 2 with rotational, translational, and a combination of rotational and translational movement, Figure 1 and 5. It would have been obvious for one having ordinary skill in the art at the time of the invention to modify Bryan et al. with an inner and outer cannula with rotational and translational movement for the purpose of providing the device with cannula with a combination of rotation and translational movement.

14. Claims 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bryan et al. in view of Ritchart et al. (2002/0016555). In regard to claims 15 and 16, Bryan et al. teaches a sampling device with an inner cannula 16 and outer cannula 12 that are selectively moveable, an outer cannula 12 with a closed distal end and penetrating tip 13 and a plurality of openings 114 in the sidewall, an inner cannula 16 is aligned with openings 112 in the sidewall, a second inner cannula 24 without openings in the sidewall, and is selectively movable with respect to the outer and inner cannula.

Bryan et al lacks a channel in the sidewall for the delivery of treatment material and automated movement of the inner and outer cannula. Ritchart et al. teaches a biopsy collection device with a channel between the inner and outer cannula with a passage for the purpose of delivering treatment material, Figure 23. It would have been obvious for one having ordinary skill in the art at the time of the invention to modify Bryan et al. with a channel in the second inner cannula as taught by Ritchart et al. for the purpose of providing a channel for delivering treatment material and automating the movement between the inner and outer cannula.

15. Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank et al. in view of Ott (6733479). Burbank et al. shows a bone marrow sampling device including a second inner element disposed between the fist inner and first outer cannula, but lacks disclosure regarding if the second inner element is a cannula. Ott teaches a sampling device that includes an outer and inner cannula 21 and 14 in addition to a second inner cannula 62. (Figure 6 and 2 column 7 line 49 to column 8 line 7). In regard to claim 13 the second inner cannula is free from openings in the sidewall (Figure 6). In regard to claim 14, the second inner cannula is selectively movable with respect to the inner cannula and the outer cannula, such that the selective movement of the second inner cannula blocks or opens at least one withdrawal aperture created between the inner cannula and the outer cannula by an alignment of the at least one opening in the inner cannula with one of the openings in the outer cannula (column 7 line 49 to column 8 line 7). In regard to claim 15, Burbank et al. discloses an channel formed in the sidewall of the inner cannula for the delivery of treatment material

149, 151 (Figure 4a). Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to modify Burbank et al. with a second inner cannula without openings in the sidewall as taught by Ott for the purpose of providing a channel for the treatment of delivery material.

16. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Burbank et al. in view of Krueger. In regard to claim 18, Burbank et al. lacks indicia on the outer and inner cannula. Krueger teaches a biological tissue biopsy device with indicia 17 on the exterior surface of the inner and outer cannula for providing orientation markers (Figures 1 and 4). Therefore, it would have been obvious for one having ordinary skill in the art at the time of the invention to modify Burbank et al. with indicia on the outer and inner cannula as taught by Krueger since such modification would provide and indication of the alignment of the inner and outer cannula.

Conclusion

17. Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 04/03/2006 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristin D. Rogers whose telephone number is 571.272.7293. The examiner can normally be reached on Monday through Friday 8:00am - 4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571.272.4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KDR

MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700